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IN THE
Supreme Court of the United States
October Term, 1992

WILLIAM DAUBERT AND JOYCE DAUBERT, INDIVIDUALLY AND AS GUARDIANS AD LITEM FOR JASON DAUBERT, AND ANITA DE YOUNG, INDIVIDUALLY AND AS GUARDIAN AD LITEM FOR ERIC SCHULLER,
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS, INC.,
Respondent.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether the uniform Federal Rules of Evidence enacted by Congress in 1975 eliminated the judge-made "general acceptance" test of *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), as a ground for excluding scientific evidence.

2. Whether the lower federal courts possess inherent judicial power to create their own rules for excluding evidence which: (a) exceed those enumerated by Congress in Fed. R. Evid. 402, (b) bypass the procedural safeguards for evidence rulemaking mandated by Congress in 28 U.S.C. §§ 2071-2077, and (c) effect substantive revision of rights granted parties under state tort law.

3. Whether the lower federal courts may constitutionally delegate control over the admissibility of scientific expert opinion testimony to the editors of peer-reviewed journals, on the ground that these editors are "the recognized authorities in the field," and that such delegation is necessary to ensure that "those most qualified to assess the general validity of a scientific method will have the determinative voice."

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OPINIONS BELOW

The opinion of the United States Court of Appeals for the Ninth Circuit, affirming the district court's grant of summary judgment for respondents, is reported at 951 F.2d 1128, and is reprinted as Appendix A, at page A1. (References to the appendices bound with this Petition are styled "A___".) The memorandum decision and order of the United States District Court for the Southern District of California, from which appeal was taken, is reported at 727 F. Supp. 570, and is reprinted as Appendix B, at page A6.

JURISDICTION

The decision of the Court of Appeals was announced on December 20, 1991. A timely petition for rehearing and suggestion for rehearing *en banc* was denied on April 8, 1992. See Appendix C, at page A16. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY AND CONSTITUTIONAL PROVISIONS INVOLVED

The Federal Rules of Evidence were enacted by Congress as a statute in 1975, Pub. L. No. 93-595, 88 Stat. 1926 (1975), 28 U.S.C app. (1988). Rule 402 provides:

Rule 402. Relevant Evidence Generally Admissible; Irrelevant Evidence Inadmissible

All relevant evidence is admissible, except as otherwise provided by the Constitution of the United States, by Act of Congress, by these rules, or by other rules prescribed by the Supreme Court pursuant to statutory authority. Evidence which is not relevant is not admissible.

Rule 702 of the Federal Rules of Evidence provides:

Rule 702. Testimony by Experts

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

28 U.S.C. § 2071 (1988) provides, in relevant part:

§ 2071. Rule-making power generally

(a) The Supreme Court and all courts established by Act of Congress may from time to time prescribe rules for the conduct of their business. Such rules shall be consistent with Acts of Congress and rules of practice and procedure prescribed under section 2072 of this title.

(b) Any rule prescribed by a court, other than the Supreme Court, under subsection (a) shall be prescribed only after giving appropriate public notice and an opportunity for comment. Such rule shall take effect upon the date specified by the prescribing court and shall have such effect on pending proceedings as the prescribing court may order.

28 U.S.C. § 2072 (1988) provides, in relevant part:

§ 2072. Rules of procedure and evidence; power to prescribe.

(a) The Supreme Court shall have the power to prescribe general rules of practice and procedure and rules of evidence for cases in the United States district courts (including proceedings before magistrates thereof) and courts of appeals.

(b) Such rules shall not abridge, enlarge or modify any substantive right. All laws in conflict with such rules shall be of no further force and effect after such rules have taken effect.

The Rules of Decision Act, 28 U.S.C. § 1652 (1988) provides, in relevant part:

§ 1652. State laws as rules of decision.

The laws of the several states, except where the Constitution or treaties of the United States or Acts of Congress otherwise require or provide, shall be regarded as rules of decision in civil actions in the courts of the United States, in cases where they apply.

The Seventh Amendment to the United States Constitution provides:

> In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by jury, shall be otherwise re-examined in any Court of the United States, than according to the rules of the common law.

STATEMENT OF THE CASE

1. This is a products liability case falling under diversity jurisdiction and governed by California law. The facts leading to the lawsuit are not disputed. Minor petitioners Jason Daubert and Eric Schuller were born with severe and permanent limb-reduction birth defects. Their parents, also petitioners in this Court, filed suit in California state court against respondent Merrell Dow Pharmaceuticals, Inc. ("Merrell"), alleging that the birth defects had been caused by Bendectin, a prescription anti-nausea drug marketed by Merrell. Each of the children's mothers had taken Bendectin during the limb-development phase of pregnancy, and no other identifiable risk factor was present. Eight experts put forward their testimony in support of the petitioners' allegation that Bendectin had caused both sets of limb defects. (A11.) Merrell elected to remove the cases, given the diversity of citizenship, to the United States District Court for the Southern District of California.

2. After preliminary discovery, Merrell moved for summary judgment in the district court on the issue of causation. In its filing under Fed. R. Civ. P. 56(e), Merrell claimed that there exists no scientific proof that Bendectin causes birth defects, and therefore that it could not have caused the birth defects at issue in the case. The sole admissible evidence introduced by Merrell in support of this proposition consisted of the conclusion of one expert witness, whom petitioners conceded was qualified to state an opinion concerning the effect of Bendectin on birth defects. Dr. Steven H. Lamm, a pediatrician, stated in a two-page affidavit that he had read all epidemiological data collected and published in medical and scientific journals which related to

estimating the effect of Bendectin on mass populations. Dr. Lamm then stated:

> Based on my review of the scientific literature, I conclude that maternal use of Bendectin during the first trimester of pregnancy is not a risk factor for human birth defects in general, for limb reduction defects specifically, or for any other particular human birth defect.

Aff. dated August 1, 1989, at 2.

This ultimate statement of opinion, standing alone, constituted admissible evidence, because Rules 704(a) and 705 of the Federal Rules of Evidence permit qualified experts to state their opinions on an ultimate issue of fact without disclosing the facts or data underlying their opinions. Dr. Lamm did provide several paragraphs of elaboration about the sorts of inquiries into the available epidemiological data that had led him to his ultimate opinion that Bendectin use is not a risk factor. But neither the underlying data nor detail about those inquiries was entered into evidence. They were not part of the admissible summary judgment record at all, but simply served to enhance the credibility of Dr. Lamm's opinion. Dr. Lamm freely and informally referred to these outside sources as permitted by Rule 703 of the Federal Rules of Evidence, which (as the Ninth Circuit has expressly agreed with other circuits) functions as "the expert testimony exception to the hearsay rules." *United States v. Unruh*, 855 F.2d 1363, 1376 (9th Cir. 1987), *cert. denied*, 488 U.S. 974 (1988).[1]

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[1] *See also Rogers v. Raymark Industries, Inc.*, 922 F.2d 1426, 1429-30 (9th Cir. 1991) ("an expert opinion may be based on any type of evidence commonly used in the field"); *United States v. Lundy*, 809 F.2d 392, 395-96 (7th Cir. 1987) ("hearsay and third-party observations that are of a type normally relied upon by an expert in the field are properly utilized by such an expert in developing an expert opinion"); *Mannino v. International Manufacturing Co.*, 650 F.2d 846, 851 (6th Cir. 1981) ("[t]he purpose of Rule 703 is to make available to the expert all of the kinds of things that an expert would normally rely upon in forming an opinion, without requiring that these be admissible in evidence"; through it "the law is catching up with the realities of professional life"); *Clinchfield R.R. Co. v. Lynch*, 784 F.2d 545, 553-544 (4th Cir. 1986) (on Rule 703 showing that data are "regularly relied upon" by experts in field, questions going to weight should be "'attacked by cross examination and refutation'").

As required by Fed. R. Civ. P. 56(e), petitioners opposed summary judgment with affidavits from expert witnesses, skilled in several relevant scientific and medical disciplines. Merrell readily conceded that each of the eight experts was qualified to state an opinion concerning the effect of Bendectin on birth defects. One of petitioners' experts, Dr. John Palmer, a medical professor and physician specializing in pharmacology, concluded:

> I have also examined the medical records pertaining to the Daubert and Schuller children and it is my opinion within a reasonable degree of medical certainty that in each case the drug Bendectin was taken at the period of time so as to [affect] the cells that would produce the normal limb structure and that Bendectin did cause the limb defects in each of the children.

Aff. dated Sept. 22, 1989, at ¶ 14. Under Fed. R. Evid. 704(a) and 705, this ultimate statement of opinion about causation from a qualified expert, standing alone, was sufficient to serve as admissible proof of causation.

The credibility of Dr. Palmer's opinion was enhanced, however, by several pages of elaboration on his reasoning and on his consideration of data from four standard sources of information about whether particular substances cause birth defects: (1) *in vitro* animal tests on animal cells, (2) *in vivo* animal tests on live animals, (3) analysis of chemical structure, and (4) analysis of data contained in the same published epidemiological studies considered by Merrell's experts. As with the sources of data relied on by Merrell's contrary expert, the sources relied on by Dr. Palmer were not themselves entered into evidence. Rather, Dr. Palmer referred to these outside sources pursuant to Fed. R. Evid. 703. Petitioners also submitted the affidavits of seven other concededly qualified experts drawn from a variety of fields related to birth defects, including teratology (the study of substances that produce malformations in human fetuses), pathology, chemistry, developmental biology, pharmacology, toxicology, embryology, dysmorphology and epidemiology. These seven affidavits demonstrated to the district court the evidence petitioners proposed to offer in order to enhance the credibility of Dr. Palmer's ultimate opinion at trial. (*See* A11-A13 (summarizing proffered testimony.))

3. The district court granted summary judgment on the basis that none of petitioners' expert testimony was admissible, "because it lacks the sufficient foundation necessary under FRE 703." In doing so, the district court cited decisions rendered by the D.C. Circuit and the First Circuit in Bendectin cases involving different plaintiffs and different evidence. *See* note 2, *infra*. The cases cited by the district court utilized Rule 703 to uphold exclusion of plaintiffs' expert causation testimony on the basis that either: (1) the testimony excluded epidemiological data; or (2) the testimony included epidemiological data but plaintiffs' expert did not cite a specific, published, peer-reviewed study which, considered in isolation, proves causation with "statistical significance," i.e., 95 percent certainty. (A8-A10, A13-A15.)[2]

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[2] As the district court summarized its holding: "The federal courts have held that epidemiological studies are the most reliable evidence of causation in this area. Accordingly, expert opinion which is not based on epidemiological evidence is not admissible to establish causation because it lacks the sufficient foundation necessary under FRE 703. Therefore, expert testimony concluding that Bendectin causes limb reduction defects which is generally based upon *in vitro* studies, chemical structure analyses and animal studies is insufficient to take the issue to the jury. The plaintiffs' experts must be competent to testify that some epidemiological study or recalculation shows a statistically significant relationship between the ingestion of Bendectin and birth defects and that this study forms the basis of their opinion." (A13-A14 (citing *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, *modified*, 884 F.2d 166 (5th Cir. 1989), *cert. denied*, 110 S. Ct. 1511 (1990) (sufficiency-of-evidence holding); *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 110 S. Ct. 218 (1989) (Rule 703 holding); *Lynch v. Merrell--National Labs.*, 830 F.2d 1190 (1st Cir. 1987) (Rule 703 holding).)

The district court added: "The defendants have introduced evidence that no epidemiological study ever performed has concluded that the use of Bendectin by pregnant woman has a statistically significant association to birth defects in those women's children. . . . The plaintiffs argue that the absence of statistically significant epidemiological studies does not disprove the fact that Bendectin causes limb reduction defects. However, this argument directly contradicts the holdings of *Brock*, *Richardson* and *Lynch*. The plaintiffs have the burden of proof, and they must come forward with statistically significant epidemiological evidence. The plaintiffs claim that Dr. Gross performed a new epidemiological study on Bendectin, but this is false. He simply recalculated a previously published study and tried to show that there actually was a significant relation between Bendectin and birth defects. Dr. Gross' 'study' was apparently never published or subjected to peer review, and nowhere does it state that Bendectin sales increased the relative risk of limb reduction defects to a level significantly above 1.0 with a confidence interval that did not include unity. Dr. Gross alleges that this 'study' shows 'a statistically significant association that is highly significant,' but his allegation and this evidence is insufficient to take this matter to a jury. Similarly, Dr. Swan's unsupported allegation that the Jick data 'statistically significantly associates Bendectin and limb defects' is similarly insufficient." (A14-A15 (citations omitted).)

4. On appeal in the Ninth Circuit, petitioners attacked the district court's exclusion of their expert testimony under Rule 703, arguing among other things that the legal construction of Rule 703 borrowed by the district court from the two other circuits was incorrect. Petitioners argued that this construction conflicted with the Third Circuit's recent decision in *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941 (3d Cir. 1990), and with established Ninth Circuit precedent, *see* page 4 & note 1, *supra*.

The Ninth Circuit below, affirming the district court's grant of summary judgment, declined to review these legal arguments concerning Rule 703. Instead, it advanced its own ground for excluding petitioners' expert testimony -- the judge-made "*Frye* rule" -- and held that the exclusion of all of petitioners' expert testimony was proper because that testimony had failed to meet the strictures of *Frye*. As the Ninth Circuit explained the rule:

> Expert opinion based on a scientific technique "is admissible if it is generally accepted as a reliable technique among the scientific community." *United States v. Solomon*, 753 F.2d 1522, 1526 (9th Cir. 1985) (citing *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923)). We impose this requirement because such evidence "creates a substantial danger of undue prejudice or of confusing the issues or of misleading the jury . . . because of its aura of special reliability and trustworthiness." *United States v. Amarel*, 488 F.2d 1148, 1152 (9th Cir. 1973); *see also* Learned Hand, *Historical and Practical Considerations Regarding Expert Testimony*, 15 HARV.L.REV. 40, 50-52 (1901).
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> * * *

> For expert opinion based on a given scientific methodology to be admissible, the methodology cannot diverge significantly from the procedures accepted by recognized authorities in the field. If it does so diverge, it cannot be shown to be "generally accepted as a reliable technique," *Solomon*, 753 F.2d at 1526, and a district court must exclude it.

(A2-A3.)

The "methodology" that the Ninth Circuit found problematic under the *Frye* test was what the court called "the reanalysis methodology employed by plaintiffs' experts" in analyzing the epidemiological data contained in published studies. (A5.) Rather than restating the published *conclusion* of each epidemiological study, plaintiffs' experts looked at the *underlying data* in the studies, applied less stringent certainty standards, and pooled data from various studies to minimize the effect of random variation affecting any one study. By so doing, plaintiffs' experts were able to offer an opinion contrary to that of the original authors of the studies. That is, through careful analysis of the original data in each study juxtaposed by consideration of the data in other studies, plaintiffs' experts were able to disagree with the original authors and conclude that the data on balance provided substantial evidence of causation. The Ninth Circuit did not rule against the legitimacy of this "reanalysis methodology." Rather, the court found *Frye* unsatisfied simply because plaintiffs' experts had not published their conclusions in peer-reviewed journals before submitting their affidavits in court:

> Plaintiffs argue that reanalysis is a generally accepted scientific technique, so it follows that their experts were basing their opinions on a permissible methodology. But the reanalysis of epidemiological studies is generally accepted by the scientific community only when it is subjected to verification and scrutiny by others in the field. Plaintiffs' reanalyses do not comply with this standard; they were unpublished, not subjected to the normal peer review process, and generated solely for use in litigation. It does not suffice that the expert's methodology meet *some* of the requirements imposed by the scientific community; it must meet *all* of the essential requirements. Selective borrowing from generally accepted scientific methodology does not satisfy *Solomon*'s rigorous standard.

(A4-A5 (citation and footnote omitted; emphasis in original).)

The Ninth Circuit's reasoning was in accord with the philosophy of restrictive admissibility underlying the *Frye* rule, as expressed by the D.C. Circuit which invented it, *see* pp. 22-23, *infra*:

> [T]he *Frye* standard retards somewhat the admission of proof based on new methods of scientific investigation by requiring that they attain sufficient currency and status to gain the general acceptance of the relevant scientific community. This is not to say, however, that the *Frye* standard exacts an unwarranted cost. The requirement of general acceptance in the scientific community assures that those most qualified to assess the general validity of a scientific method will have the determinative voice.

United States v. Addison, 498 F.2d 741, 743-44 (D.C. Cir. 1974) (footnotes omitted). The Ninth Circuit candidly recognized, however, that use of the judge-made *Frye* rule is not a universal practice, as revealed by the Third Circuit's decision in *DeLuca*. Reviewing that decision, the Ninth Circuit expressly noted the conflict between its holding and the Third Circuit's position:

> Because the Third Circuit has specifically rejected the *Frye/Solomon* 'generally accepted' standard, *United States v. Downing*, 753 F.2d 1224, 1236-37 (3d Cir. 1985), we find the court's analysis in *DeLuca* to be contrary to our established precedent and decline to follow it.

(A4 n.2.)

REASONS FOR GRANTING THE WRIT

1. This Court Should Resolve the Interminable Circuit Conflict Over Whether the Judge-Made *Frye* Rule Has Survived the Enactment of the Federal Rules of Evidence

This is the third case before this Court in recent months presenting an issue on which the lower federal courts have been unable to agree: whether the judge-made rule of *Frye v. United*

States, 293 F. 1013 (D.C. Cir. 1923), was eliminated as a ground for excluding evidence by Congress's enactment of uniform Federal Rules of Evidence. The *Frye* rule was designed to withhold novel but otherwise admissible scientific evidence from juries until the underlying methodologies gain "general acceptance" among scientists in the field, and the continued vitality of this rule is an issue that has long divided the circuits.

As early as 1986, two Justices of this Court noted a split among three circuits over the status of *Frye*. *See United States v. Mustafa*, 22 M.J. 165 (C.M.A.), *cert. denied*, 479 U.S. 953 (1986) (White, J., joined by Brennan, J., dissenting) (recommending grant of certiorari "to resolve this conflict on an obviously recurring and important issue"). Today, at least six circuits (including the Ninth Circuit below) hold that judicial use of *Frye* is allowable under the Federal Rules of Evidence.[3] By contrast, three other circuits have held that the *Frye* test is incompatible with the expert testimony provisions because

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[3] The other five circuits are:

Fifth Circuit: *Christophersen v. Allied Signal Corp.*, 939 F.2d 1106, 1115-16 (5th Cir. 1991) (per curiam), *cert. denied*, 112 S. Ct. 1280 (1991). *See* pp. 11-13, 17 & n.5, *infra*.

Sixth Circuit: *United States v. Metzger*, 778 F.2d 1195, 1203 (6th Cir. 1985), *cert. denied*, 477 U.S. 906 (1986) (stating that "[a]lthough '[a] number of the federal courts have responded to the enactment of Rule 702 by rejecting the *Frye* standard, [this circuit] still predicate[s] the admission of scientific evidence on general acceptance in the community'") (quoting academic commentary).

Seventh Circuit: *United States v. Smith*, 869 F.2d 348, 351 (7th Cir. 1989) (stating that "[a]lthough the validity of the judge-made rule in *Frye* has been criticized by some courts and commentators for numerous reasons, this circuit has continued to affirm (and to apply) the *Frye* standard").

Eighth Circuit: *United States v. Two Bulls*, 918 F.2d 56, 60 & n.7 (8th Cir. 1990) (refusing to reject use of *Frye* in evaluation of "the admissibility of any questionable opinion evidence").

D.C. Circuit: *United States v. Shorter*, 809 F.2d 54, 59-61 (D.C. Cir.), *cert. denied*, 484 U.S. 817 (1987) (reaffirming that "*Frye* is still the law of this Circuit").

Congress designed the Rules to override judge-made restrictions on expert testimony, leaving juries responsible for evaluating possible weaknesses in scientific and other expert testimony in both criminal and civil cases.[4]

In March, 1992, this Court was faced with the *Frye* issue in a petition seeking review of a bitter 8-to-5 split within the *en banc* Fifth Circuit in a diversity case, *Christophersen v. Allied Signal Corp.*, 939 F.2d 1106 (5th Cir. 1991) (per curiam), *cert. denied*, 112 S. Ct. 1280 (1991). *See* Petition for Certiorari, No. 91-785. In his Fifth Circuit concurrence in the result of that case, Chief Judge Clark vigorously opposed any use of *Frye*: "[I]f *Frye* is a rule of evidence, it has not survived the enactment of the Federal Rules of Evidence. . . . [I]f it is a substantive rule, its adoption in diversity cases is foreclosed by *Erie*." 939 F.2d at 1120 (Clark, J., concurring in the result) (citations omitted). Chief Judge Clark also "completely agree[d]," *ibid.*, with the views of four dissenters in that case that the Fifth

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[4] In one of the earliest decisions to move away from *Frye*, the Fourth Circuit commented: "Unless an exaggerated popular opinion of the accuracy of a particular technique makes its use prejudicial or likely to mislead the jury, it is better to admit relevant scientific evidence in the same manner as other expert testimony and allow its weight to be attacked by cross-examination and refutation." *United States v. Baller*, 519 F.2d 463, 466 (4th Cir.), *cert. denied*, 423 U.S. 1019 (1975).

The Third Circuit, in *United States v. Downing*, 753 F.2d 1224, 1232-37 (3rd Cir. 1985), surveyed the history of *Frye* and of the academic and judicial commentary, summarized *Frye*'s "serious flaws" -- notably "its vagueness and its conservatism" -- and concluded that *Frye* "should be rejected as an independent controlling standard of admissibility" because it "reflects a conservative approach to the admissibility of scientific evidence that is at odds with the spirit, if not the precise language, of the Federal Rules of Evidence." *Id.* at 1236-37. The Third Circuit reaffirmed its rejection of *Frye* in *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 955 (3d Cir. 1990) (the precedent noted by the Ninth Circuit below, *see* A4 n.2), stating: "We [explicitly rejected *Frye* in *Downing*], for among other reasons, because the general acceptance test was too vague and malleable to yield consistent results, and because its nose-counting emphasis often led to the exclusion of helpful evidence in contradiction to the spirit of the Federal Rules of Evidence." *Id.* at 955.

The Second Circuit recently rejected any use of *Frye* in *United States v. Jakobetz*, 955 F.2d 786, 794-97 (2d Cir. 1992). *See* pages 13-16, *infra*.

Circuit was vastly expanding the scope of the *Frye*, without authority in this Court's precedents and directly contrary to this Court's jurisprudence under *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938). *See* 939 F.2d at 1132-33 & n.41, 1134-36 & n.48 (Reavley, J., dissenting). Nevertheless, the *en banc* majority in *Christophersen* relied on *Frye* to uphold exclusion of an expert opinion. 939 F.2d at 1115-16.

Despite *Christophersen*'s fervent *en banc* debate over the legitimacy of applying *Frye* as a rule for excluding evidence, especially in diversity cases, *Christophersen* did not prove to be a suitable vehicle for certiorari on the issue, for at least two reasons. First, the Opposition to Certiorari in *Christophersen* stressed that "for the Court to reach the *Frye* issue in this case, it must first consider and hold" for petitioners on other, fact-bound evidentiary issues; the Opposition therefore urged this Court to deny review and wait for "a case in which the *Frye* issue will be necessarily and directly addressed." Opp. at 8-9. Second, the Opposition noted that a Judicial Conference committee was then seriously considering a major revision to Fed. R. Evid. 702 designed to "allow courts to 'reject testimony that is based upon premises lacking any significant support and acceptance within the scientific community, or that otherwise would be only marginally helpful to the fact-finder.'" Opp. at 8 (quoting commentary to proposed revision). *See also Federal Rules: Major Changes Sought By Judicial Conference Working Group*, 60 U.S.L.W. 2158 (1991), at 2158. The Opposition, at 8, argued that adoption of this codification of the *Frye* principle would "eliminate any precedential value of this case" and that a grant of certiorari would therefore be premature.

Ultimately, this Court denied review in *Christophersen*. 112 S. Ct. 1280 (March 2, 1992). Nevertheless, two Justices sketched the current circuit conflict over *Frye* and urged review of the issue. *Id.* at 1281 (White, J., joined by Blackmun, J., dissenting) (observing that "the appropriate standard for determining the admissibility of expert testimony . . . is an issue that has long divided the federal courts and here deeply divided the Court of Appeals for the Fifth Circuit, sitting *en banc*. . . . Because this is an important and recurring issue, I would grant certiorari to resolve the conflict.") (citation omitted).

The proposed revision to Fed. R. Evid. 702 encountered substantial opposition and subsequent to this Court's denial of review in *Christophersen*, on June 20, 1992, the Standing Committee in charge of revisions declined, by a 7-to-4 vote, to advance the proposal to the Judicial Conference for further consideration. *See* BNA Daily Report for Executives, June 23, 1992 (available on NEXIS, 1992 DER 121 d31).

Although *Christophersen* was unsuitable for this Court's resolution of the *Frye* conflict, two petitions for certiorari (including this petition) that necessarily and directly address the *Frye* issue are presently pending before this Court. Both cases were mentioned as part of the description of the circuit conflict in the *Christophersen* dissent from denial of certiorari. *See* 112 S. Ct. at 1281 (White, J., joined by Blackmun, J., dissenting).

The petition in case No. 91-7921, *Jakobetz v. United States*, a criminal case, seeks review of the Second Circuit's refusal to follow other circuits in requiring prosecutors to meet *Frye*'s heightened standard for admissibility when seeking to introduce new forms of forensic evidence. *See* note 3, *supra* (listing circuits); page 23-24, *infra* (sketching prosecutorial burden). In *Jakobetz* the Second Circuit rejected a criminal defendant's claim that prosecutors should have been forced to prove that the "DNA fingerprinting" evidence used against him enjoyed "general acceptance" in the field. In the process the Second Circuit reaffirmed its early abandonment of the *Frye* rule and, in particular, rejected the Eighth Circuit's application of *Frye* to DNA fingerprinting. *United States v. Jakobetz*, 955 F.2d 786, 794-97 (2d Cir. 1992).

Jakobetz reviewed a district court's decision to admit testimony based on the new technique of "DNA fingerprinting," first introduced in 1988, which relies on person-to-person differences in DNA and which "has been widely hailed as a revolutionary forensic tool that takes some of the uncertainty [as to identity] out of criminal convictions." Gina Kolata, *Critic of "Genetic Fingerprint" Test Tells of Pressure to Withdraw Paper*, N.Y. Times, Dec. 20, 1991, at A20, col. 4. Recent public criticisms by some scientists of the reliability of DNA fingerprinting have raised alarm in the law enforcement community, since under *Frye* "DNA evidence cannot be admitted in evidence

unless the [government] establishes that there is a *consensus* among scientists that it is valid." *Ibid.* (emphasis added). Some state courts and the Eighth Circuit have relied on *Frye* to limit sharply the use of DNA evidence, given the absence of such scientific consensus. *See, e.g., Fight Erupts Over DNA Fingerprinting*, 254 Science 1721 (Dec. 20, 1991); Rorie Sherman, *DNA Evidence Dispute Escalates*, Nat'l L.J., Jan. 20, 1992, at 3, col. 1; Gina Kolata, *Chief Says Panel Backs Courts' Use of a Genetic Test*, N.Y. Times, Dec. 20, 1991, at A1, col. 1.

The Second Circuit avoided all these difficulties by reaffirming an earlier ruling that *Frye* has no place in the Federal Rules of Evidence. The defendant's arguments for use of *Frye*, the Second Circuit noted, asserted a "very real danger that the critical faculties" of lay jurors can be "overwhelmed by the highly technical features of forensic DNA testing" and an inability of the jury to "independently and critically scrutinize technical DNA evidence when confronted by the testimony of experts," which can create an "'aura of mystic infallibility.'" 955 F.2d at 796. The Second Circuit rejected these elitist arguments for using the *Frye* rule or any other "general acceptance" rubric, holding: "Although we realize that DNA evidence does present special challenges, we do not think that they are so special as to require a new standard of admissibility. Despite the difficulties involved in cases with novel, complex and confusing evidence, the jury must retain its fact-finding function." *Id.* at 796. The court "agree[d] with both Professor McCormick and Judge Weinstein" that continued use of the restrictive *Frye* rule is inconsistent with the Federal Rules of Evidence. *Id.* at 797. The Second Circuit also expressly rejected the extremely stringent *Frye* test applied to DNA fingerprinting by the Eighth Circuit in *United States v. Two Bulls*, 918 F.2d 56 (8th Cir. 1990), in which the Eighth Circuit denied the government's request for a holding that the Federal Rules of Evidence supersede *Frye*. *Id.* at 795-96. The Ninth Circuit's decision below embraced the same "aura of mystic infallibility" justification for the *Frye* test that the Second Circuit rejected, as the Ninth Circuit expressed its concern about the "'aura of special reliability and trustworthiness'" supposedly surrounding expert testimony. (A2.)

The *Jakobetz* petition No. 91-7921 asks this Court to resolve

this Second Circuit-Eighth Circuit conflict over the treatment of DNA evidence and more generally, with reference to *Frye*, emphasizes that "[t]he circuits are divided over the issue of what standards to employ in determining the admissibility of novel scientific evidence in general." Petition at 15 (citations omitted). In his response to this petition, the Solicitor General has frankly agreed that there is a deep circuit conflict over the *Frye* issue presumably worthy of this Court's review, and he has furnished a succinct and neutral summary of that circuit conflict:

> Petitioner contends (Pet. 13-18) that there is a conflict among the courts of appeals regarding the correct standard for determining the admissibility of evidence based on novel scientific techniques . . . . As petitioner correctly notes (Pet. 15), the courts of appeals are divided as to the correct standard for determining the admissibility of expert testimony based on novel scientific evidence. The admissibility of such testimony in federal court is governed by Fed. R. Evid. 702, which permits "a witness qualified as an expert by knowledge, skill, experience, training or education" to testify concerning "scientific, technical, or other specialized knowledge" if the testimony "will assist the trier of fact to understand the evidence or to determine a fact in issue." Some courts of appeals have decided that admissibility of novel scientific evidence under Rule 702 should turn on its relevance and materiality and on whether it will assist the jury to resolve factual issues at trial, not exclusively on the degree to which it has gained general acceptance in the scientific community. . . . Other courts of appeals have continued to apply the threshold test first articulated in *Frye*, in which the court held that expert testimony based on novel scientific theories or discoveries is admissible only if there has been a preliminary showing that the theory or discovery is "sufficiently established to have gained general acceptance in the particular field in which it belongs."

Brief for the United States in Opposition, No. 91-7921, filed June 10, 1992, at 8-10 (extensive citations omitted).

The Solicitor General's opposition to review in *Jakobetz* flowed not from doubt about the importance of the circuit conflict thus presented but instead from concern about the petitioner's apparent lack of a real stake in the controversy:

> Because the court of appeals believed that the DNA profiling evidence in this case was admissible under *Frye* as well as under *Williams* [its decision rejecting *Frye*], this is not an appropriate case in which to resolve the issue [on] which the courts of appeals are in conflict.

Opp. at 12. The Solicitor General, however, did suggest a fundamental agreement with the Second Circuit's rejection of the *Frye* rule: "Rule 702 of the Federal Rules of Evidence does not . . . suggest that the standard for admissibility of novel scientific evidence should be more stringent than the standard that applies to other forms of expert testimony." Opp. at 14.

Assuming that the *Jakobetz* petition is indeed less than ideal for this Court's consideration of the status of *Frye*, the circuit conflict highlighted by the Solicitor General can be decided by the instant petition which presents squarely the holding of the Ninth Circuit -- in premeditated conflict with the Third Circuit, now joined by the Second Circuit -- that the *Frye* test is a permissible rule for excluding evidence.

Prompt resolution of this circuit conflict is essential to vindicating one of Congress's most fundamental policy choices in enacting the Federal Rules of Evidence -- its desire to bring *uniformity* to federal evidence law. The Senate Report accompanying the bill that became the Federal Rules of Evidence cited the need for "a comprehensive code of evidence intended to govern the admissibility of proof in all trials before the Federal courts because of the lack of uniformity and clarity in the present law of evidence on the Federal level." S. Rep. No 93-1277, 93rd Cong., 2d Sess. (1974), at [1974] U.S. Code Cong. & Ad. News 7054. Persistence of the current conflict can only encourage the type of forum-shopping that prevailed under the pre-1975 system in which judges in each jurisdiction crafted and applied their own common-law rules of evidence. Absent a resolution of this conflict parties will increasingly recognize that the rules of evidence now determine the ultimate outcome of their cases, particularly in so-called "mass tort" cases, and claims will be decided not on their merits but rather on the ability of lawyers to maneuver them into courts with friendly rules for scientific evidence. This trend will neither ease existing burdens on federal courts nor encourage efficient and fair resolution of cases.

This conflict has a profound impact on the ultimate outcomes of civil and criminal cases in federal courts nationwide, and this conflict will *not* go away. When this Court, over the dissents of two Justices, declined in 1986 to review the status of *Frye*, *see United States v. Mustafa*, 22 M.J. 165 (C.M.A.), *cert. denied*, 479 U.S. 953 (1986), there might have been good reason to expect that the Third Circuit's comprehensive and powerful *Downing* opinion -- announced in 1985 (*see* note 4, *supra*) -- would win acceptance in other circuits and avoid any need for this Court's review. But inter-circuit disputes have only sharpened, and grounds for reconciliation have disappeared. The tenor of the current conflict is illustrated by the *en banc* Fifth Circuit's much-noted reinvigoration of the *Frye* test in *Christophersen*,[5] and by the Ninth Circuit's equally vigorous embrace of *Frye* in the instant case, followed quickly by the Second Circuit's complete rejection of *Frye* in the *Jakobetz* case. Waiting another Term or longer would not further ventilate the issues and would only guarantee additional frustration of Congress's core goal of ensuring uniform rules of evidence in the federal courts.

2. This Court Should Decide Whether the Lower Federal Courts Possess Inherent Judicial Power to Create Their Own Rules for Excluding Evidence

The Ninth Circuit's decision below stretches the concept of "inherent judicial power" well beyond the breaking point,

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[5] *See, e.g.*, Recent Case, 105 Harv. L. Rev. 791, 795 (1992) (observing that "the real import of [*Christophersen*] is that it breathes new life into the *Frye* rule and counters 'the movement away from the general acceptance test'") (citation omitted); Note, *"Helpful" or "Reasonably Reliable"?: Analyzing the Expert Witness's Methodology Under the Federal Rules of Evidence 702 and 703*, 77 Cornell L. Rev. 350, 382 & n.215 (1992) (noting that "the per curiam opinion [in *Christophersen*] relies on an innovative application of the much-maligned *Frye* test," and that "[a]pplication of *Frye* to a run-of-the-mill civil case is unquestionably a new concept"); *Fifth Circuit Formulates Stiff Test For Admitting Toxic Tort Expert Opinion*, 60 U.S.L.W. 1042 (Sept. 17, 1991); Taylor, *Expert Witness Opinion Eyes; Circuits Split on the Issue*, National Law Journal, Oct. 21, 1991, at 3.

trampling over Congress's express displacement of that power in Fed. R. Evid. 402. In so doing, the decision bypasses the procedural safeguards for evidence rulemaking set forth by Congress in 28 U.S.C. §§ 2071-2077, and it effects substantive revision of rights granted petitioners under state tort law in violation of this Court's *Erie* jurisprudence which must in this context supersede whatever inherent judicial power could otherwise be exercised.

The instant case therefore presents this Court with an opportunity to speak with a united voice concerning the limits of inherent judicial power, a subject which engendered a 5-to-4 split in the recent case of *Chambers v. NASCO, Inc.*, 111 S. Ct. 2123 (1991). The majority in *Chambers* ruled that the scheme of statutes and rules provided by Congress to target bad-faith conduct had not "displace[d] the inherent power to impose sanctions" for such activity. *Id.* at 2134. Although on the facts of the case the majority did not perceive "that the District Court's reliance on the inherent power thwarted the purposes of the other sanctioning mechanisms," *id.* at 2136, the majority reaffirmed that "[b]ecause of their very potency, inherent powers must be exercised with restraint and discretion," *id.* at 2132, and that "the exercise of the inherent power of lower federal courts can be limited by statute and rule, for '[t]hese courts were created by act of Congress.'" *Id.* at 2134 (citation omitted). The majority also reaffirmed that any exercise of inherent powers must not violate the twin aims of this Court's *Erie* jurisprudence, of discouraging forum-shopping and avoiding inequitable administration of the laws. *Id.* at 2137.

Justice Kennedy, in dissent, also emphasized that "[i]nherent powers are the exception, not the rule, and their assertion requires special justification in each case," and that the lower federal courts must not be permitted "to ignore express Rules and statutes on point." *Id.* at 2143 (Kennedy, J., joined by Rehnquist, C.J. and Souter, J., dissenting). Strongly focusing on the *Erie* point, Justice Kennedy expressed concern that permitting use of inherent powers to impose sanctions for prelitigation primary conduct "violates the fundamental tenet of federalism announced in *Erie* by regulating primary behavior that the Constitution leaves to the exclusive province of States," with the

result that "[r]espondent's decision to bring this suit in federal rather than state court resulted in a significant expansion of the substantive scope of his remedy," a "result prohibited by *Erie* and the principles that flow from it." *Id.* at 2148-49. Justice Scalia also voiced serious concerns, arguing among other things that "Congress may prescribe the means by which the courts may protect the integrity of their proceedings," and that "[a] court must use the prescribed means unless for some reason they are inadequate." *Id.* at 2140-41 (Scalia, J., dissenting).

The Ninth Circuit has refused to recognize that its power to impose the *Frye* test has been displaced by enactment of the Federal Rules of Evidence and related procedural rulemaking requirements laid down by Congress. That refusal and the Ninth Circuit's imposition of the *Frye* test to significantly reduce the substantive scope of petitioners' tort remedies under California law in a diversity case reveal a fundamental lack of respect for the limits on inherent judicial power. Such disrespect provides common ground for the majority and dissenting Justices in *Chambers* and presents an important opportunity for this Court to underscore to the lower federal courts basic axioms regarding the limits of judicial power.

The power of the federal courts -- including even *this* Court -- "to prescribe rules of procedure and evidence for the federal courts exists only in the absence of a relevant Act of Congress." *Palermo v. United States*, 360 U.S. 343, 353 n.11 (1959). Congress possesses the authority under the Necessary and Proper Clause "to enact laws carrying into execution the powers vested in other departments of the Federal Government," *Kaiser Aetna v. United States*, 444 U.S. 164, 172 n.7 (1979), including an "undoubted power to regulate the practice and procedure of federal courts." *Sibbach v. Wilson & Co.*, 312 U.S. 1, 9 (1941).

Unlike the loosely constructed corpus of sanctions law considered in *Chambers*, the law of evidence has been comprehensively and rigorously addressed by Congress, and Congress has spoken specifically to the issue of which grounds justify the exclusion of relevant evidence. By failing to list judge-made rules of exclusion, Congress has displaced the sort of inherent judicial authority which the Ninth Circuit below purports to exercise. In Fed. R. Evid. 402 Congress decreed:

> All relevant evidence is admissible, except as otherwise provided [1] by the Constitution of the United States, [2] by Act of Congress, [3] by these rules or [4] by other rules prescribed by the Supreme Court pursuant to statutory authority. Evidence which is not relevant is not admissible.

(Brackets added).

This list does not contain the *Frye* test or any other customized admissibility limits applied by the lower federal courts prior to enactment of the Rules, and by some circuits notwithstanding Congress's direction still today. Indeed, the *only* judge-made rules that Congress decided to permit under Rule 402 are rules promulgated by *this Court* "pursuant to statutory authority" -- that is, its authority to enact rules conferred by 28 U.S.C. § 2071(a), subject to all the elaborate procedural requirements of 28 U.S.C. §§ 2071-2977. *See* page 2, *supra*. Congress pointedly refused to authorize the courts of appeals or the district courts to make their own supplementary evidence rules even after notice-and-comment rulemaking pursuant to 28 U.S.C. § 2071. Any inference that Congress nevertheless left the lower federal courts free to do the same thing through *decisional law* that bypasses all these procedural constraints is ruled out by the wording of Fed. R. Evid. 501. With Rule 501, Congress created an exception to the general ban on decisional rules of exclusion by permitting development of a federal law of privileges under "the principles of the common law as they may be interpreted by the courts of the United States in the light of reason and experience." Congress knew the precise words to use when it wished to authorize new decisional rules of evidence exclusion, and Congress failed to use such words in the area of expert testimony, governed by Rules 701 to 706 of the Federal Rules of Evidence.

Apart from the exact and exacting language chosen, the function of Rule 402 is obvious: it carries out Congress's central goal of bringing uniformity and coherence to federal evidence law. Rule 402 is "'the keystone to the whole scheme,'" designed both "to sweep away all pre-existing rules of exclusion" and "to modify this sweeping repeal by stating the relationship between the repealer and the pre-existing law as well as making clear that the rest of the Evidence Rules are exceptions to the basic rule of

relevance." 22 Charles Alan Wright & Kenneth W. Graham, Jr., *Federal Practice and Procedure: Evidence* § 5192, at 177 (1978).

Analysis of the purpose animating Rule 402, of course, is hardly necessary. Even if the *Frye* rule had been universally embraced and applied by all circuits prior to the enactment of the Federal Rules of Evidence it could not have survived given the language of those Rules. To have displaced *Frye* Congress need not have "really meant" to do so. Such is the clear teaching of Chief Justice Rehnquist's opinion for the Court in *Bourjaily v. United States*, 483 U.S. 173 (1987), which considered the status of the long-established common-law "bootstrapping rule" under the co-conspirator exception to the hearsay rule. The common-law bootstrapping rule had always barred hearsay statements *themselves* from being used to prove conspiracy and to thereby trigger the co-conspirator exception to the prohibition on hearsay, because without the bootstrapping rule, "'hearsay would lift itself up by its own bootstraps to the level of competent evidence.'" *Id.* at 177 (citation omitted). Addressing whether the bootstrapping rule had survived enactment of the Federal Rules of Evidence, Chief Justice Rehnquist noted Rule 104(a)'s provision that when deciding the admissibility of evidence, a trial court "is not bound by the rules of evidence except those with respect to privileges," and he observed: "That would seem to many to be the end of the matter. Congress has decided that courts may consider hearsay in making these factual determinations." *Id.* at 177-78.

Chief Justice Rehnquist then stated:

> But petitioner nevertheless argues that the bootstrapping rule, as most Courts of Appeals have construed it, survived this apparently unequivocal change in the law unscathed and that Rule 104, as applied to the admission of co-conspirator's statements, does not mean what it says. We disagree.
>
> Petitioner claims that Congress evidenced no desire to disturb the bootstrapping rule, which was embedded in the previous approach, and we should not find that Congress altered the rule without affirmative evidence so indicating. It would be extraordinary to require legislative history to *confirm* the plain meaning of Rule 104.

Id. at 178 (emphasis in original).

Bourjaily is hardly an isolated exception. This Court has consistently taken the approach that the Federal Rules of Evidence are to be interpreted just like any other statute, with no judicial license for extra creativity. *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 163 (1988) ("[b]ecause the Federal Rules of Evidence are a legislative enactment, we turn to the 'traditional tools of statutory construction,' in order to construe their provisions") (citation omitted). *See generally* Jonakait, *The Supreme Court, Plain Meaning, and the Changed Rules of Evidence*, 68 Tex. L. Rev. 745 (1990). Yet this message has been largely lost on the lower courts, including the Ninth Circuit below; only a handful of circuit court opinions have cited the *Rainey* decision or noted that the Federal Rules of Evidence are a statute. One of the few lower federal court opinions to heed this vital admonition is *United States v. Rogers*, 918 F.2d 207, 209 (D.C. Cir. 1990) (Thomas, J.) (recognizing that on evidence questions a court must "begin as . . . with any statute, with the language of the rules themselves").

Despite the instruction of both Congress and this Court, the court below has chosen to advance its own concerns about appropriate evidence policy by brazenly enacting what must be viewed as a judicial amendment to the Federal Rules of Evidence in the Ninth Circuit. The Ninth Circuit's attempt to function as "a sort of junior-varsity Congress," *Mistretta v. United States*, 488 U.S. 361, 427 (1988) (Scalia, J., dissenting), should be overturned.

A total of six circuits persist in applying the judge-made *Frye* rule despite congressional displacement of the rule. *See* note 3, *supra*. But two of these courts -- including the Ninth Circuit below -- have further exceeded their judicial authority by using the accident of their diversity jurisdiction to impose on the citizens of the various States within their circuits a federal rule of decision that strikes at the heart of this Court's doctrine under *Erie Railroad v. Tompkins*, 304 U.S. 64 (1938).

Until recently, use of the *Frye* rule in federal court was almost entirely limited to criminal trials of federal statutory crimes. *Frye* itself was a criminal case, in which the D.C. Circuit refused to admit evidence obtained from a predecessor of

the modern polygraph, on the basis that authorities in the field had not yet accepted the polygraph machine technique as valid, and thus that "'inexperienced persons are unlikely to prove capable of forming a correct judgment upon it.'" 293 F. at 1014 (quoting defense brief). The court's test of admissibility was *ad hoc* (as the court could find no cases bearing on admissibility) and notoriously vague, reading in full:

> Just when a scientific principle or discovery crosses the line between the experimental and demonstrable stages is difficult to define. Somewhere in this twilight zone the evidential force of the principle must be recognized, and while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.

Ibid.

The D.C. Circuit later explained that "the *Frye* test protects prosecution and defense alike by assuring that a minimal reserve of experts exists who can critically examine the validity of a scientific determination in a particular case." *United States v. Addison*, 498 F.2d 741, 743 (D.C. Cir. 1974). For many years, tied to this original criminal law context, the *Frye* test was employed to bar from federal criminal trials a host of scientific evidence involving new and complicated technologies, primarily to protect criminal defendants from evidence that might be overvalued by the jury.[6] Prior to its radical alteration of its *Frye* test in the decision below, the Ninth Circuit itself recognized this core feature of *Frye*. *See United States v. Fleishman*, 684 F.2d 1329, 1337 (9th Cir.), *cert. denied*, 459 U.S. 1044 (1982) (stating that special rules like the *Frye* test were created in criminal cases out of a "concern[] with the possible prejudice to

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[6] Examples include the forward-looking infrared imaging system, *see United States v. Kilgus*, 571 F.2d 508, 510 (9th Cir. 1978); "voiceprints," *see Addison, supra*, 498 F.2d at 743; neutron activation analysis, *see United States v. Stifel*, 433 F.2d 431, 436 (6th Cir. 1970), *cert. denied*, 401 U.S. 994 (1971); and sodium pentothal ("truth serum"), *see Lindsey v. United States*, 237 F.2d 893, 896 (9th Cir. 1956).

the defendant's right to a fair trial of admitting testimony of purported experts based upon insufficiently substantiated scientific theories, techniques or tests"). Before the enactment of the Federal Rules of Evidence, and given the acknowledged responsibility of the lower federal courts to ensure the orderly and fair conduct of criminal proceedings, there was perhaps little basis for questioning the institutional legitimacy of the *Frye* rule and no basis for scrutiny under *Erie*.

The recent decision of the *en banc* Fifth Circuit in *Christophersen* and of the Ninth Circuit in the decision below has pioneered a vastly expanded version of the *Frye* test in civil diversity litigation that acts as a means of cutting short the opportunity for civil trials based on a perception that particular expert *reasoning* is "too novel." So utilized, the *Frye* rule represents a shocking violation of "[t]he *Erie* rule [which] remains a vital expression of the federal system and the concomitant integrity of the separate States." *Ferens v. John Deere Co.*, 110 S. Ct. 1274, 1280 (1990) (per Kennedy, J.).

The *Christophersen* decision rested on an innovative and expansive application of *Frye* to an unremarkable state tort case. *See* note 5, *supra*. Sketching the judicial activism at play, Chief Judge Clark stressed that "[u]ntil today, this circuit has limited *Frye* to a narrow class of federal criminal cases to which *Erie* does not apply." 939 F.2d at 1120 (Clark, J., concurring in the result). Furthermore, the four dissenters (with the agreement of Chief Judge Clark) noted that the *en banc* majority had extended the matters to which *Frye* was applied beyond bare consideration of "novel device[s] or technique[s]" to "subject[] expert reasoning to judge-determined reliability." 939 F.2d at 1132 (Reavley, J., dissenting). In other words, an expert reasoning from routine sources of information would be scrutinized to determine whether his final *conclusions* are "acceptable," that is, consistent with the views of many or most other scientists. As Judge Reavley explained the *Erie* problems posed by this transformation:

> Until today, we soundly limited the *Frye* doctrine to particular techniques, "novel scientific evidence," that reflect the factual context of *Frye*. To my knowledge, the Fifth Circuit has never excluded otherwise relevant evidence strictly on the basis of lack of general scientific acceptance.

> To do so would impose a significantly heavier burden of proof and persuasion on the offering party.

Id. at 1133 (citations omitted).

Such a regime of special presumptions -- barring a finding of causation until a judicially determined quantum of proof can be mustered by a party through experts whose conclusions are drawn from standard sources which enjoy "general scientific acceptance" -- clearly effects "substantive" constraints within the meaning of the *Erie* doctrine. *See, e.g., Dick v. New York Life Ins. Co.*, 359 U.S. 437, 446-47 (1959); *Cities Service Oil Co. v. Dunlap*, 308 U.S. 208 (1939). As the *Christophersen* dissenters concluded, such rules are so decisive in nature that their imposition "substantially affect[s] the rights of claimants and the proof required for their compensation." 939 F.2d at 1135 (Reavley, J., dissenting). As the dissenters pointed out, "[u]nder Texas law, claimants [did] not suffer these disadvantages," and thus there was "no doubt that in Texas courts Mrs. Christophersen would have received her jury trial." *Id.* at 1135-36 & n.48. "This lack of congruence with the state courts in cases dependent on our diversity jurisdiction," the dissenters argued, "is fundamentally at odds with the Supreme Court's decision in *Erie*. As a result, we encourage reverse forum shopping and deprive plaintiffs of the substantive rights that should be available to them under state law." *Id.* at 1137-38 (King, J., dissenting). The decision of the Ninth Circuit below suffers from precisely the same defect under *Erie*.

In elaborating on their own variant of the *Frye* test "for determining the underlying reliability of a new scientific technique," first announced in the criminal case of *People v. Kelly*, 549 P.2d 1240, 1244 (Cal. 1976), California courts have consistently rejected use of the *Frye* test in the manner dictated by the Ninth Circuit decision below. The leading case is *People v. McDonald*, 690 P.2d 709, 723-24 (Cal. 1984), in which the California Supreme Court overruled a trial court's refusal to permit a psychologist to testify concerning data on the asserted unreliability of eyewitness testimony. Focusing on the trial court's ruling that such testimony "is not yet 'scientific enough' to be admissible," the California Supreme Court stated:

It is important to distinguish in this regard between *expert testimony* and *scientific evidence*. When a witness gives his personal opinion on the stand -- even if he qualifies as an expert -- the jurors may temper their acceptance of his testimony with a healthy skepticism born of their knowledge that all human beings are fallible. But the opposite may be true when the evidence is produced by a machine: like many laypersons, jurors tend to ascribe an inordinately high degree of certainty to proof derived from an apparently "scientific" mechanism, instrument or procedure. . . . "[T]he rule serves its salutary purpose of preventing the jury from being misled by unproven and ultimately unsound scientific methods."

Here, by contrast, no such methods are in issue. We have *never* applied the *Kelly-Frye* rule to expert medical testimony, even when the witness is a psychiatrist and the subject matter is as esoteric as the reconstitution of a past state of mind or the prediction of future dangerousness, or even the diagnosis of an unusual form of mental illness not listed in the diagnostic manual of the American Psychiatric Association . . . .

Id. at 724 (emphasis added) (citations omitted). Subsequent decisions have ruled that expert medical testimony on the cause of an injury cannot be subjected to the *Frye* rule, even where such testimony is novel and unsupported by published scientific studies.[7]

The *Frye* test imposed by the Ninth Circuit on the citizens of California directly flouts *McDonald* and subsequent decisions by

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[7] *See also People v. Pitts*, 223 Cal.App.3d 606, 865 (1990) ("there is a difference between development of a new scientific technique -- a novel method of proof -- and development of a body of medical knowledge and expertise. . . . The expression of an expert medical opinion as to the cause of a wound or injury falls outside of the realm of what is subject to the *Kelly-Frye* rule") (citation omitted); *McCleery v. City of Bakersfield*, 170 Cal.App.3d 1059, 1071 (1985) (applying *McDonald* rule to admit scientific opinions even though "the proffered testimony in the instant case was novel -- the trial court characterized appellants' efforts as 'trying to plow new ground in this case' -- and was not backed by extensive scientific literature and scholarly studies as was the proffered testimony in *McDonald*").

imposing *Frye*'s "general acceptance" requirement to preclude from jury consideration the conclusions put forth in the testimony of qualified medical experts as to the cause of petitioners' limb defects. Even though the "reanalysis of epidemiological studies" relied on in part by some of petitioners' experts "is generally accepted by the scientific community," (A4), the Ninth Circuit excluded all the opinions from evidence and ended the entire case because the opinions had not been "subject to verification and scrutiny by others in the field" through the peer-review publication process. The Ninth Circuit mandated that the opinions "meet *all* of the essential requirements . . . [to] satisfy [the Ninth Circuit's] rigorous standard." (A4-A5.) This "rigorous standard" is in flat violation of *Erie* and the Rules of Decision Act, which together "mandate[] that a federal court sitting in diversity apply the substantive law of the forum State, absent a federal statutory or constitutional directive to the contrary." *Salve Regina College v. Russell*, 111 S. Ct. 1217, 1218 (1991) (citing *Erie*, 304 U.S. at 78; 28 U.S.C. § 1652 (Rules of Decision Act)). Because the decision below permits Merrell to disable future California Bendectin cases merely by removing them to federal court it violates *Erie*'s "twin aims" of discouraging forum-shopping and avoiding inequitable administration of the laws. *See Chambers*, *supra*, 111 S. Ct. 2123, 2137 (1991) (majority opinion). *See also id.* at 2148-49 (Kennedy, J., dissenting); *Stewart Organization, Inc. v. Ricoh Corp.*, 108 S. Ct. 2239, 2248-50 (1988) (Scalia, J., dissenting). These fundamental issues merit this Court's plenary attention.

3. This Court Should Decide Whether the Lower Federal Courts May Delegate Control Over Admissibility of Scientific Expert Opinion Testimony to the Editors of Peer-Reviewed Journals

The final issue warranting review is the Ninth Circuit's use of the *Frye* rule to delegate control over admissibility of scientific expert opinion testimony to the editors of peer-reviewed journals. *See* pp. 7-9, *supra*. Under the decision below, if an expert witness wishes to rely upon his own analysis of data in a published scientific study, but after full study reaches a conclu-

sion opposite that of the author of the study, he may offer his opinion *only* if that opinion "is subjected to verification and scrutiny by others in the field" (A4) through the peer-review process *and* can convince the editors of a peer-review journal to publish the analysis. (A5.) The court below regarded this as a wise requirement, on the basis that the peer review process "is one of the hallmarks of reliable scientific investigation" -- that "'the science of publication, replication, and verification, the science of consensus and peer review'" is "'good science'" and "'the best test of certainty we have.'" (A5 & n.3 (citation omitted).) This requirement mandates that such opinions may be presented to a jury only if "accepted by recognized authorities in the field" (A3), in accord with the central aim of the *Frye* rule of "assur[ing] that those most qualified to assess the general validity of a scientific method will have the determinative voice." *United States v. Addison*, 498 F.2d 741, 744 (D.C. Cir. 1974).

The Ninth Circuit's requirement that opinions be published in peer-reviewed journals before they can be presented at trial, and the concomitant delegation of substantial authority over evidence in federal trials to the private editors of these journals, is a blatant abuse of judicial power. There is absolutely no language in any relevant statute or rule authorizing such a requirement. To be sure, whether or not an expert's conclusions are peer-reviewed and published may well affect the credibility of his testimony. The Ninth Circuit urged an "added dose of skepticism" especially where studies are performed in anticipation of litigation. (A5 n.3.) But our system of justice entrusts such practical grounds for skepticism of a witness's testimony to the jury -- not to judges, and not to private journalists anointed by judges -- and the Seventh Amendment bars the strange rule imposed by the court below.[8]

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[8] "Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of the judge," *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986), and by displacing these jury functions the decision below violates the Seventh Amendment. The Ninth Circuit's delegation of credibility assessments to the editors of peer-reviewed journals obviously has no conceivable analogue in procedural law circa 1791 and therefore cannot survive constitutional scrutiny. *Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 336-37 (1979). The Seventh Amendment's history makes clear that its central mission is to check the power of autocratic, life-tenured federal judges by entrusting factual disputes to empaneled jurors who are independent of the sovereign's judges, however inefficient this can be at times. *See id.* at 337-56 (Rehnquist, J., dissenting); *see also Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33, 83 (1989) (White, J., dissenting) ("'The function of the civil jury is to diffuse the otherwise autocratic power and authority of the judge'").

As the Ninth Circuit below acknowledged (A4 n.2), its decision is in conflict with the Third Circuit's decision in *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941 (3d Cir. 1990), a conflict that independently merits this Court's review.[9]

Lacking in any legal support, the rule imposed below is equally lacking in scientific support. The Ninth Circuit is profoundly mistaken in regarding the peer-reviewed publication process as built on a "search for truth," so that it may logically serve the truth-seeking function of the trial process. As a former editor of the *Journal of the American Medical Association* has remarked, "[p]eer review is far from being a 'perfect sausage machine for grinding out the truth.' . . . 'Just because peer review is about a review of scientific data doesn't mean that it is itself a scientific process. . . . We need more realistic, human expectations.'" L.A. Times, May 22, 1989, Pt. II, at 3 col. 1 (quoting Elizabeth Knoll). The editor-in-chief of *The New England Journal of Medicine* agrees that "the peer review process is 'not meant to determine ultimate truth or falsity.' [I]ts main functions [are] 'to improve the quality of what is published' and 'to help editors decide what they want to publish in their journals . . . .'" *Ibid.* (quoting Dr. Arnold S. Relman). As numerous commentators have documented, neither the objectives of peer review nor its procedures are suited to the determination

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[9] On the issue of whether a court may insist that an expert go through peer-review and publication before presenting his opinion, *DeLuca* rejected the theory that "an expert [must] accept the conclusions reached by the authors of studies if the expert wishes to utilize the data underlying those studies as a basis for testimony." 911 F.2d at 954. It held, further, that: "[T]he Federal Rules of Evidence contain no requirement that an expert's testimony be based upon reasoning subjected to peer-review and published in the professional literature." *Ibid.*

of truth.[10] The Ninth Circuit's bizarre "publish-or-perish" edict for expert testimony is bad law and bad science, has no place in federal jurisprudence, and merits prompt review.

CONCLUSION

For all these reasons, certiorari should be granted.

Respectfully submitted,

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July 7, 1992

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[10] *See, e.g.*, Charles W. McCutchen, *Peer Review: Treacherous Servant, Disastrous Master*, Technology Review, Oct. 1991, at 28 ("Science uses peer review to determine which projects to pay for and which articles to publish, and, recently, to judge cases of alleged misconduct"), 30 ("Peer review resists investigation. Only insiders know the details of each decision. They may not tell the truth"), 33 ("Unfortunately, the power of referees, usually anonymous, permits self-interest, jealousy, revenge, and other unworthy motives to influence decisions"); Jonathan Schlefer, *Truth, Beauty, and Peer Review*, Technology Review, Oct. 1990, at 5 ("Our society often wants to see peer review as a mechanical certification of truth for which no one has to take responsibility. No such mechanism is conceivable"); Lawrence K. Altman, M.D., *The Doctor's World: Peer Review is Challenged*, N.Y. Times, Feb. 25, 1986, at C3 col. 1 ("[R]eferees are often selected as part of 'an old-boy network' rather than randomly as a scientific process might do. Since many journals are run on shoestring budgets, the possibilities of conflicts of interest in the peer review process seem apparent. One potential conflict that has received too little attention is between medical journal editors and the drug companies whose advertising they depend on for income"); Lawrence K. Altman, *Study Says Drug Ads in Medical Journals Frequently Mislead*, N.Y. Times, June 1, 1992, at A1, col. 1 ("In 1991, drug companies spent $351 million on advertisements in medical journals").

The combined effect of all these influences is reflected in a recent *New York Times* article which spotlighted a five-year delay in publication of a dissenting "re-analysis" of the efficacy of a frequently prescribed drug, resulting from "academia s surprising aversion to dissent," "the strong ties between scientific journals, academia and the drug industry," and "professional jealousies." *See Hidden Discord Over Right Therapy*, N.Y. Times, Dec. 24, 1991, at B6 col. 1.

APPENDICES

APPENDIX A

Decision of the United States Court of Appeals for the Ninth Circuit, affirming the district court's grant of summary judgment for respondent, dated December 20, 1991 ..... A1

APPENDIX B

Memorandum Decision and Order of the United States District Court for the Southern District of California, granting summary judgment for respondent, dated November 1, 1989 ..... A6

APPENDIX C

Order of the Ninth Circuit, denying rehearing, dated April 8, 1992 ..... A18

APPENDIX A

UNITED STATES COURT OF APPEALS
For the Ninth Circuit

No. 90-55397

WILLIAM DAUBERT; JOYCE DAUBERT, individually and as Guardians Ad Litem for JASON DAUBERT, a minor; ANITA DE YOUNG, individually, and As Guardian Ad Litem for ERIC SCHULLER,

Plaintiffs-Appellants,

v.

MERRELL DOW PHARMACEUTICALS, INC., a Delaware corporation,

Defendant-Appellee.

Appeal from the United States District Court
For the Southern District of California

(December 20, 1991)

Before: Alex Kozinski and Diarmuid F. O'Scannlain, Circuit Judges, and Stephen M. McNamee,* District Judge.

KOZINSKI, Circuit Judge:

Plaintiffs Jason Daubert and Eric Schuller suffer from limb reduction birth defects. They allege that these defects resulted

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* The Honorable Stephen M. McNamee, United States District Judge for the District of Arizona, sitting by designation.

from the fact that their mothers used Bendectin, a prescription anti-nausea drug, during pregnancy. The plaintiffs seek damages from the drug's manufacturer, defendant Merrell Dow Pharmaceuticals.

Plaintiffs' evidence of causation consisted primarily of expert opinion based on *in vitro* and *in vivo* animal tests, chemical structure analyses and the reanalysis of epidemiological studies. Among the contrary evidence proffered by Merrell Dow was the affidavit of a physician and epidemiologist who reviewed all of the available literature on the subject, which included more than 30 published studies involving over 130,000 patients, and concluded that no published epidemiological study had demonstrated a statistically significant association between Bendectin and birth defects. Plaintiffs do not challenge this summary of the published record.

The district court determined that plaintiffs could not meet their burden of proving that Bendectin caused Jason's and Eric's birth defects and granted Merrell Dow's motion for summary judgment. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 727 F. Supp. 570 (S.D. Cal. 1989).

A. Expert opinion based on a scientific technique "is admissible if it is generally accepted as a reliable technique among the scientific community." *United States v. Solomon*, 753 F.2d 1522, 1526 (9th Cir. 1985) (citing *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923)). We impose this requirement because such evidence "creates a substantial danger of undue prejudice or of confusing the issues or of misleading the jury . . . because of its aura of special reliability and trustworthiness." *United States v. Amarel*, 488 F.2d 1148, 1152 (9th Cir. 1973); *see also* Learned Hand, *Historical and Practical Considerations Regarding Expert Testimony*, 15 HARV.L.REV. 40, 50-52 (1901). Moreover, whether expert opinion can satisfy this requirement is reviewed *de novo* by an appellate court, for "the answer to the question about the reliability of a scientific technique or process does not vary according to the circumstances of each case. It is therefore inappropriate to view this

threshold question of reliability as a matter within each trial judge's individual discretion." *Reed v. State*, 391 A.2d 364, 367 (Md. 1978); *see also United States v. Williams*, 583 F.2d 1194, 1197-1201 (2d Cir. 1978) (applying *de novo* review to the question of the general acceptance of a scientific technique), *cert. denied*, 439 U.S. 1117 (1979).

For expert opinion based on a given scientific methodology to be admissible, the methodology cannot diverge significantly from the procedures accepted by recognized authorities in the field. If it does so diverge, it cannot be shown to be "generally accepted as a reliable technique," *Solomon*, 753 F.2d at 1526, and a district court must exclude it. If such evidence is admitted and materially affects the verdict, a judgment supported by this evidence cannot stand. *See Lindsey v. United States*, 237 F.2d 893, 897-98 (9th Cir. 1956).

B. Whether Bendectin is responsible for limb reduction defects is not a new question in the federal courts. Four of our sister circuits have considered whether plaintiffs could establish such responsibility in the absence of critically analyzed epidemiological studies establishing a connection between the use of the drug and the birth defects. *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941 (3d Cir. 1990); *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, *modified*, 884 F.2d 166 (5th Cir. 1989), *cert. denied*, 110 S. Ct. 1511 (1990); *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 110 S. Ct. 218 (1989); *Lynch v. Merrell-National Labs.*, 830 F.2d 1190 (1st Cir. 1987) (opinion by Noonan, J., sitting by designation). Three circuits have concluded that the plaintiffs could not establish such a link. Considering largely the same evidence presented to the district court below, these courts held that the animal and chemical studies were insufficient to establish a link between Bendectin and birth defects, *Brock*, 874 F.2d at 313-15; *Richardson*, 857 F.2d at 830; *Lynch*, 830 F.2d at 1194, in part because the plaintiffs' own experts acknowledged the need to verify such data with epidemiological evidence.

Brock, 874 F.2d at 314; *Richardson*, 857 F.2d at 830.[1] These courts were unwilling to allow plaintiffs to rely on reanalyses of epidemiological studies because these reanalyses had neither been published nor subjected to the rigors of peer review. They found the methodology particularly problematic in light of the massive weight of the original published studies supporting the defendant's position, all of which had undergone full scrutiny from the scientific community. *See Brock*, 874 F.2d at 312-13; *Richardson*, 857 F.2d at 831; *Lynch*, 830 F.2d at 1193-96; *see also Christophersen v. Allied-Signal Corp.*, 939 F.2d 1106, 1111 n.8 (5th Cir. 1991) (en banc).[2]

Plaintiffs argue that reanalysis is a generally accepted scientific technique, so it follows that their experts were basing their opinions on a permissible methodology. But the reanalysis of epidemiological studies is generally accepted by the scientific community only when it is subjected to verification and scrutiny by others in the field. *See* Dore, *A Commentary on the Use of Epidemiological Evidence in Demonstrating Cause-in-Fact*, 7 HARV.ENV'L L.REV. 429, 438-39 (1983) (discussing requirements for original epidemiological studies). Plaintiffs' reanalyses do not comply with this standard; they were unpublished, not subjected to the normal peer review process, and generated solely for use in litigation.[3] It does not suffice that the expert's methodology meet *some* of the requirements imposed by the scientific community; it must meet *all* of the essential requirements. Selective borrowing from generally accepted scientific methodology does not satisfy *Solomon*'s rigorous standard.

[1] *Richardson* and *Lynch* held that expert testimony that Bendectin caused birth defects, based solely on animal and chemical tests and reanalyses of epidemiological studies, was inadmissible under Federal Rule of Evidence 703, and that therefore plaintiffs had failed to present evidence to support a jury verdict in their favor. 857 F.2d at 830-831; 830 F.2d at 1193-96. *Brock* did not hold that the plaintiffs' expert testimony was inadmissible, but did decide that it was insufficient to support the jury's verdict. 874 F.2d at 315.

[2] The Third Circuit has left open the possibility that expert testimony based on the reanalysis of epidemiological studies may be admissible if it can be shown to be reliable and not too likely to overwhelm, confuse or mislead the jury. *See DeLuca*, 911 F.2d at 955 (remanding case for district court to reconsider the admissibility of plaintiffs' expert testimony). Because the Third Circuit has specifically rejected the *Frye/Solomon* "generally accepted" standard, *United States v. Downing*, 753 F.2d 1224, 1236-37 (3d Cir. 1985), we find the court's analysis in *DeLuca* to be contrary to our established precedent and decline to follow it.

C. *Lynch*, *Richardson* and *Brock* reflect a well-founded skepticism of the scientific value of the reanalysis methodology employed by plaintiffs' experts; they recognize that "the best test of certainty we have is good science -- the science of publication, replication, and verification, the science of consensus and peer review." P. Huber, *Galileo's Revenge: Junk Science in the Courthouse*, 228 (1991). For the convincing reasons articulated by our sister circuits, we agree with the district court that the available animal and chemical studies, together with plaintiffs' expert reanalysis of epidemiological studies, provide insufficient foundation to allow admission of expert testimony to the effect that Bendectin caused plaintiffs' injuries. Accordingly, plaintiffs could not satisfy their burden of proving causation at trial. *See Christophersen*, 939 F.2d at 1109 ("When the contested evidence is essential to the cause of action and the trial court has excluded the evidence, we may decide the appeal . . . solely on the basis of the soundness of the evidentiary ruling. For if we uphold the exclusion of essential evidence, the [review of the summary judgment ruling] becomes academic.").

AFFIRMED.

[3] Scientific studies conducted in anticipation of litigation must be scrutinized much more carefully than studies conducted in the normal course of scientific inquiry. This added dose of skepticism is warranted, in part, because studies generated especially for use in litigation are less likely to have been exposed to the normal peer review process, which is one of the hallmarks of reliable scientific investigation. *See Brock*, 874 F.2d at 313; *Richardson*, 857 F.2d at 831 n.55; *Perry v. United States*, 755 F.2d 888, 892 (11th Cir. 1985).

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT
OF CALIFORNIA

WILLIAM DAUBERT, et al., *Plaintiffs*,	)	
v.	)	
MERRELL DOW PHARMACEUTICALS, INC., et al., *Defendants*.	)	CIVIL NOS. 84-2013-G(IEG), 84-2929-G(IEG) (Consolidated)
MICHAEL SCHULLER et al., *Plaintiffs*,	)	
v.	)	
MERRELL DOW PHARMACEUTICALS, INC., et al., *Defendants*.	)	

MEMORANDUM DECISION AND ORDER

EARL B. GILLIAM, UNITED STATES DISTRICT JUDGE:

The defendant's motion for summary judgment was scheduled for hearing on October 6, 1989, in Courtroom 7 before the Honorable Earl B. Gilliam. Plaintiffs were represented by Mary Gillick and Barry Nace. George Berry, Robert Dickson and Pamela Yates appeared on behalf of defendant. Having considered the points and authorities and oral argument of counsel, the court issues this memorandum decision and order granting defendant's motion for summary judgment.

FACTS

This case involves personal injuries sustained by plaintiffs. Infant plaintiffs and their guardians ad litem seek damages from defendant for injuries (limb reduction birth defects) allegedly sustained as a result of the mothers' ingestion of Bendectin during pregnancy. Bendectin is a prescription pharmaceutical product previously manufactured by Merrell Dow, indicated solely for the treatment of nausea and vomiting during pregnancy. Defendant has moved for summary judgment, arguing that plaintiffs have failed to sustain their burden of establishing a genuine issue of material fact regarding causation.

DISCUSSION

Summary judgment is proper "after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial. . . ." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). "[T]h[e] standard [for granting summary judgment] mirrors the standard for a directed verdict under Federal Rule of Civil Procedure 50(a). . . ." *Id.* at 323 (citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986)).

In this case the defendant has moved for summary judgment. Plaintiffs, who have the burden of proof by a preponderance of the evidence, oppose the motion. The court must therefore determine "whether a fair-minded jury could return a verdict for the plaintiff [based] on the evidence presented." *Anderson v. Liberty Lobby, Inc.* 477 U.S. at 251-252. The court must view the evidence in a light most favorable to plaintiff, however, "[t]he evidence is insufficient if the strongest inference to be drawn in the plaintiff's favor is that defendant's negligence could *possibly* have been the cause of the accident." *Bieghler v. Kleppe*, 633 F.2d 531, 533 (9th Cir. 1980) (emphasis in original) (citing *Neely v. St. Paul Fire & Marine Insurance Co.*, 584 F.2d 341, 345 (9th Cir. 1978)). The plaintiff must show that defendant's negligence "was more probably than not the proximate cause of the accident" to defeat summary judgment and take the

issue to a jury. *Bieghler* at 533. The court should exclude inadmissible evidence objected to by either party prior to ruling upon the motion. *See, Hollingsworth Solderless Terminal Co., v. Turley* 622 F.2d 1324, 1335 (9th Cir. 1980).

Federal Rule of Evidence (FRE) 703, restricts the admissibility of scientific evidence. "A necessary predicate to the admission of scientific evidence is that the principle upon which it is based 'must be sufficiently established to have general acceptance in the field to which it belongs.'" *United States v. Kilgus*, 571 F.2d 508, 510 (9th Cir. 1978). Therefore, expert opinion not based on facts or data "of a type reasonably relied upon by experts in the particular field" is not helpful, but instead is confusing or misleading and should therefore be excluded. *See*, Fed.R.Evid. 403. *See also Barrel of Fun, Inc. v. State Farm Fire and Casualty Co.*, 739 F.2d 1028, 1033 (5th Cir. 1984) (excluding expert's opinion based on polygraph test). "Whether an expert's opinion has an adequate basis, and whether without it an evidentiary burden has been met, are matters of law for the court to decide." *Richardson v. Richardson-Merrell*, 857 F.2d 823, 829 (D.C.Cir. 1988), *cert. denied*, 107 L.Ed. 2d 171 (1989).

There are two schools of thought governing expert testimony in these Bendectin cases, and one seems to be prevailing in the federal courts. Unfortunately for the plaintiffs, the prevailing school of thought warrants summary judgment in this case.

The prevailing school is best exemplified by *Brock v. Merrell Dow Pharmaceuticals*, 874 F.2d 307 (5th Cir. 1989), *modified*, 884 F.2d 166 (5th Cir. 1989), *rehr'g denied, en banc*, 884 F.2d 167 (5th Cir. 1989) where the court held the following:

> We find, in this case, the Brocks' failure to present statistically significant epidemiological proof that Bendectin causes limb reduction defects to be fatal to their case.

Id. at 313. The court also noted:

> Hopefully, our decision will have the effect of encouraging district judges faced with medical and epidemiological proof

> in subsequent toxic tort cases to be especially vigilant in scrutinizing the basis, reasoning, and statistical significance of studies presented by both sides. However, we do not wish this case to stand as a bar to future Bendectin cases in the event that new and statistically significant studies emerge which would give a jury a firmer basis on which to determine the issue of causation.

Id. at 315. Several other cases are in accord with this reasoning. *See, Richardson v. Richardson-Merrell, supra; Lynch v. Merrell-National Laboratories*, 830 F.2d 1190 (1st Cir. 1987); *Hull v. Merrell Dow Pharmaceuticals, Inc.*, 700 F.Supp. 28 (S.D.Fla. 1988); *In Re Richardson-Merrell, Inc. "Bendectin" Products Liability Litigation*, 624 F.Supp. 1212 (S.D.Ohio 1985), *aff'd*, 857 F.2d 290 (6th Cir. 1988), *cert. denied* 109 S.Ct. 788 (1989); *Thompson v. Merrell Dow Pharmaceuticals, Inc.*, 229 N.J.Super. 230, 551 A.2d 177 (1988).

In medical cases like this one, courts must "critically evaluate the reasoning process by which the experts connect data to their conclusions in order for courts to consistently and rationally resolve the disputes before them." *Brock*, 874 F.2d at 310. Absent a scientific understanding of the cause of the birth defects at issue in Bendectin cases, causation may be shown only through reliance upon epidemiological evidence. *See, Richardson v. Richardson-Merrell; Lynch v. Merrell-National Laboratories. See also In Re Agent Orange Product Liability Lit.*, 611 F.Supp. 1223 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2nd Cir. 1987) (stating that epidemiological studies were "the only useful studies having any bearing on causation" in Agent Orange cases).

In *Richardson*, Dr. Done, the plaintiff's expert, relied upon 1) chemical structure activity analysis, 2) *in vitro* (test tube) studies, 3) *in vivo* (animal teratology) studies, and 4) reanalysis of epidemiology studies. He used the results of these four types of studies to conclude that within a reasonable degree of certainty, Bendectin causes birth defects. The court concluded that Dr. Done's testimony lacked an adequate scientific basis:

> These three types of studies -- chemical, *in vitro*, and *in vivo* -- cannot furnish a sufficient foundation for a conclusion that Bendectin caused the birth defects at issue in this case. Studies of this kind singly or in combination are not capable of proving causation in human beings in the face of the overwhelming body of contradictory epidemiological evidence.

Richardson, 857 F.2d at 830. The court also rejected the reanalysis of the epidemiological studies:

> Dr. Done further admitted that no one who had published work on Bendectin had concluded that there was a statistically significant association between Bendectin and limb reduction defects. . . . Only by recalculating the data was Dr. Done able to obtain what he deems a statistically significant result. Moreover, the studies rejected by Dr. Done had been published in peer-reviewed scientific journals, while Dr. Done has neither published his recalculations nor offered them for review.

Id. at 831 (emphasis added).

The plaintiffs rely on *Oxendine v. Merrell Dow Pharmaceuticals, Inc.*, 506 A.2d 1100 (D.C.App. 1986) and other cases which basically give more deference to the expert's opinion. *Oxendine* is the leading Bendectin case in this regard, and the appellate court found that Dr. Done had a sufficient foundation for his testimony when he relied upon chemical analyses, animal studies, *in vitro* studies and recalculations of epidemiological studies:

> Dr. Alan Done, appellant's sole causation witness, had testified that no conclusion about Bendectin's effect on humans could be drawn from any of the four types of scientific data upon which he principally relied when each type was considered separately from the others. The [trial] court focused on this fact and concluded that if each type of data, viewed in isolation, was not sufficient to prove that Bendectin caused birth defects, then all of them taken together could not prove it either. In so doing, the trial court erred [by granting defendant's motion for J.N.O.V.].

Oxendine, 506 A.2d at 1104. The *Oxendine* court viewed the recalculations of epidemiological studies and the varying conclusions as involving a "classic battle of the experts." *Id.* at 1110. The court refused to find that plaintiffs had provided insufficient evidence to support the jury verdict solely because they had not provided a single original or recalculated epidemiological study which showed a statistically significant association between Bendectin and birth defects. *Id.* at 1107-10.

Oxendine is definitely in the minority camp. Although there appears to be no Ninth Circuit authority directly applicable to these Bendectin cases, this court must view the authority developed by three other federal circuit courts in *Brock*, *Lynch* and *Richardson* as highly persuasive.

In this case, the plaintiffs offer the opinion testimony of eight experts to establish that Bendectin is a teratogen (it causes limb reduction defects generally), and that Bendectin ingested by the mothers during pregnancy caused the limb reduction defects suffered by the infant Daubert and Schuller plaintiffs. Those experts are Dr. Adrian Gross, Dr. Stuart Newman, Dr. Alan K. Done, Dr. Shanna Swan, Dr. Jay Glasser, Dr. Wayne Snodgrass, Dr. Johannes Thiersch and Dr. John Palmer. Plaintiffs have submitted this testimony in the form of affidavits, deposition transcripts, and transcripts from previous trials.

Dr. Adrian Gross is a licensed and accredited veterinarian with experience in pathology and toxicology. *Ealy v. Richardson-Merrell* transcript, Exhibit 26 at pages 650-60. Dr. Gross would testify at trial that to within a reasonable degree of certainty Bendectin is a teratogen. Dr. Gross would base his opinion on animal studies which allegedly show a statistically significant association between Bendectin and doxylamine succinate (a component of Bendectin) and birth defects. *Id.* at pages 834-38.

Dr. Stuart Newman is a specialist in developmental biology. *Ealy* transcript, Exhibit 21 at pages 198-203; *Newman Affidavit* at pages 1-6. Dr. Newman would testify at trial that to within a reasonable degree of certainty "Bendectin is capable of interfering with the development of the limb in the human being and causing birth defects in the developing limb of the human being and that Bendectin is a human teratogen in the normal therapeutic dose." *Newman Affidavit* at page 9. Dr. Newman would base his opinion on *in vitro* studies and the pharmacology aspects of Bendectin. *Id.*

Dr. Alan Done is a medical doctor with specialties in pediatrics, clinical pharmacology and toxicology. *Oxendine v. Richard-Merrell* transcript, Exhibit 31 at page 3. Dr. Done's profferred testimony is unclear from the materials presented, but he apparently would testify that to a reasonable degree of certainty Bendectin is a teratogen. *Id.* at 854. Dr. Done apparently would base his opinion on analyses of the chemical structure and properties of doxylamine succinate animal studies *in vivo*, *in vitro* studies, and various informal and formal human studies, including epidemiological ones. *Id.* at 853.

Dr. Shanna Swan is an epidemiologist and biostatistician practicing in the field of reproductive epidemiology. *Ealy* transcript, Exhibit 12 at pages 3523-27. Dr. Swan would testify that to a reasonable degree of certainty, it is her opinion "that considering all available data that is provided in animal, *in vitro* and epidemiological studies, including the relative risks, the confidence limits and also the power of the studies, that it is more likely than not that Bendectin is, in fact, associated with limb reduction defects." *Swan Affidavit* at page 7. Dr. Swan would base her opinion on "the methodology that is generally and reasonably relied upon by epidemiologists to analyze, study and interpret data that has been collected, published and unpublished in trying to draw opinions concerning whether or not there is a cause and effect relationship between a drug and a birth defect." *Id.* at page 7-8.

Dr. Jay Glasser is a specialist in biostatistics, epidemiology

and biometry. *Hill v. Merrell Dow* transcript, Exhibit 32 at pages 4-7; *Glasser Affidavit* at pages 1-4. Dr. Glasser would testify that "Bendectin is within a reasonable degree of epidemiological certainty associated with congenital disorders, including limb defects." *Glasser Affidavit* at page 7. Dr. Glasser would base his opinion on techniques that are generally and reasonably relied upon by biometrists, epidemiologists and biostatisticians. *Id.*

Dr. Wayne Snodgrass is an associate professor of pediatrics and pharmacology and toxicology. *Rudell v. Merrell Dow* transcript, Exhibit 20 at page 2. Dr. Snodgrass would testify that in his opinion Bendectin is a human teratogen. *Id.* at page 4. Dr. Snodgrass would base his opinion on results of various studies in several disciplines including pharmacology, toxicology, *in vitro* studies, animal studies and human studies. *Id.*

Dr. Johannes Thiersch is a specialist in pathology and pharmacology. *Thiersch Curriculum Vitae*, Exhibit 18. Dr. Thiersch would testify that the chemical composition and physiological activity of a drug are of great interest and importance in determining whether a drug is a teratogen. *Ealy v. Richardson-Merrell* transcript, Exhibit 22 at page 1596.

Dr. John Palmer is a professor of pharmacology. *Palmer Affidavit* at pages 1-4. Dr. Palmer would testify that in his opinion to a reasonable medical and scientific certainty Bendectin is a teratogen. *Id.* at page 7. Dr. Palmer would base his opinion on the pharmacological data, animal studies data, *in vitro* studies data, epidemiological data and other human data. *Id.* at pages 5-7. Dr. Palmer would also testify that he has examined the medical records of the plaintiff children and to a reasonable degree of medical certainty Bendectin was taken at a period of time such as to effect their development and it indeed caused their limb defects. *Id.* at pages 7-8.

The federal courts have held that epidemiological studies are the most reliable evidence of causation in this area. Accordingly, expert opinion which is not based on epidemiological evidence is not admissible to establish causation because it lacks the suffi-

cient foundation necessary under FRE 703. *See, Brock*, 874 F.2d at 311-15; *Richardson*, 857 F.2d at 829-32; *Lynch*, 830 F.2d at 1194. Therefore, expert testimony concluding that Bendectin causes limb reduction defects which is based upon *in vitro* generally studies, chemical structure analyses and animal studies is insufficient to take the issue to the jury. The plaintiffs' experts must be competent to testify that some epidemiological study or recalculation shows a statistically significant relationship between the ingestion of Bendectin and birth defects and that this study forms the basis of their opinion. *Id.* In this case, the plaintiffs have failed to live up to the *Brock* mandate to provide some epidemiological evidence to support their claim that Bendectin is a teratogen. *Brock*, 874 F.2d at 315.

The defendants have introduced evidence that no epidemiological study ever performed has concluded that the use of Bendectin by pregnant women has a statistically significant association to birth defects in those women's children. *Report on the Safety of Bendectin/Diclectin for Use in the Management of Nausea and Vomiting of Pregnancy*, Exhibit J, Defendant's Reply to Affidavits of Plaintiff's Experts Submitted in Opposition to Defendant's Motion for Summary Judgment, at page 2 ("Controlled studies involving over 130,000 patients have not demonstrated any reproducible or consistent association of birth defects with Bendectin exposure. In fact, the results of the epidemiological studies are just what one might expect of an agent without reproductive or teratogenic risks."). *See also Statement of Steven H. Lamm*, Exhibit A, Defendant's Memorandum of Points and Authorities in Support of its Motion for Summary Judgment on the Issue of Causation at page 1 (after reviewing the world's literature on Bendectin and human birth defects, the studies "showed no difference in the risk of birth defects between those infants whose mothers had taken Bendectin during the first trimester of pregnancy and those infants whose mothers had not"). The plaintiffs' experts agree that none of the *published* studies show a statistically significant association between the use of Bendectin and birth defects. *See, e.g., Hill v. Merrell Dow Deposition of Jay H. Glasser*, Exhibit J, Defendant's Memorandum of Points and Authorities in Support of its Motion for Summary Judgment on the Issue of Causation at page 164.

The plaintiffs argue that the absence of statistically significant epidemiological studies does not disprove the fact that Bendectin causes limb reduction defects. *See, e.g.*, Plaintiffs' Opposition to Defendant's Motion for Summary Judgment at 20-27; *Affidavit of Shanna Helen Swan* at pages 4-6. However, this argument directly contradicts the holdings of *Brock, Richardson* and *Lynch*. *See, supra*. The plaintiffs have the burden of proof, and they must come forward with statistically significant epidemiological evidence. The plaintiffs claim that Dr. Gross performed a new epidemiological study on Bendectin, but this is false. He simply recalculated a previously published study and tried to show that there actually was a significant relation between Bendectin and birth defects. *Letter to Thomas H. Bleakley*, Exhibit 40. Dr. Gross' "study" was apparently never published or subjected to peer review, and nowhere does it state that Bendectin sales increased the relative risk of limb reduction defects to a level significantly above 1.0 with a confidence interval that did not include unity. Dr. Gross alleges that this "study" shows "a statistically significant association that is highly significant" (Affidavit at page 11), but his allegation and this evidence is insufficient to take this matter to a jury. *See, Brock*, 874 F.2d at 312-13. Similarly, Dr. Swan's unsupported allegation that the Jick data "statistically significantly associates Bendectin and limb defects" (Affidavit at page 7) is similarly insufficient.

The court feels that the strongest inference to be drawn for plaintiffs based on the epidemiological evidence is that Bendectin could *possibly* have caused plaintiffs' injuries, therefore summary judgment is proper against them. *See, Bieghler v. Kleppe, supra*, 633 F.2d at 533. The court finds that there are no genuine issues of material fact with respect to causation and finds for the defendant on all causes of action.

IT IS SO ORDERED.

Dated: November 1, 1989

APPENDIX C

UNITED STATES COURT OF APPEALS
For the Ninth Circuit

No. 90-55397, D.C. No. CV-84-2013-G(I)

WILLIAM DAUBERT; JOYCE DAUBERT, individually and as Guardians Ad Litem for JASON DAUBERT, a minor; ANITA DE YOUNG, individually, and As Guardian Ad Litem for ERIC SCHULLER,

Plaintiffs-Appellants,

v.

MERRELL DOW PHARMACEUTICALS, INC., a Delaware corporation,

Defendant-Appellee.

(Filed April 8, 1992)

ORDER

Before: KOZINSKI and O'SCANNLAIN, Circuit Judges, and MCNAMEE,* District Judge.

The petition for rehearing is denied. The full court has been advised of the suggestion for rehearing en banc and no active judge has requested a vote. The suggestion for rehearing en banc is therefore rejected. Fed.R.App.P. 35(b).

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* The Honorable Stephen M. McNamee, United States District Judge for the District of Arizona, sitting by designation.